



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2018-0032; FRL-9987-83]

## Waxes and Waxy Substances, Rice Bran, Oxidized; Exemption from the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of waxes and waxy substances, rice bran, oxidized when used as an inert ingredient in pesticide formulations applied to growing crops and raw agricultural commodities after harvest, on animals, and in antimicrobial formulations (food-contact surface sanitizing solutions). Spring Trading Company, on behalf of Clariant Corporation, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of waxes and waxy substances, rice bran, oxidized in accordance with the terms of the exemptions.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2018-0032, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDfRNotices@epa.gov](mailto:RDfRNotices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2018-0032 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2018-0032, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Petition for Exemption**

In the **Federal Register** of April 11, 2018 (83 FR 15528) (FRL-9975-57), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11074) by Spring Trading Company, 203 Dogwood Trail, Magnolia, TX 77354, on behalf of Clariant Corporation. The petition requested that 40 CFR 180.910, 180.930, and 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of waxes and waxy substances, rice bran, oxidized (CAS Reg. No. 1883583-80-9) (“rice bran wax oxidized”), when used as an inert ingredient as a flow aid, surface protection, film-forming, carrier, coating agent, and adjuvant in pesticide formulations applied on growing crops and raw agricultural commodities after harvest, to animals, and in antimicrobial formulations (food-contact surface sanitizing solutions). That document referenced a summary of the petition prepared by Spring Trading Company on behalf of Clariant Corporation, the petitioner, which is available in the docket, <http://www.regulations.gov>. One comment was received on the notice of filing. EPA's response to these comments is discussed in Unit V.C.

## **III. Inert Ingredient Definition**

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons;

surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

#### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(c)(2) requires EPA to take into account the factors specified in subparagraphs (b)(2)(C) and (D) in making this safety determination. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure

to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCa section 408(c)(2)(A), and the factors specified in FFDCa section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for rice bran wax oxidized including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with rice bran wax oxidized follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by rice bran wax oxidized, as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Available studies on rice bran wax oxidized include an acute oral toxicity study, a dermal irritation study, an eye irritation study, a dermal sensitization study, and an Ames assay. No subchronic or chronic studies are available for rice bran wax oxidized. Because data on rice bran wax oxidized is limited, surrogate data on various other long chain fatty acids, long chain fatty alcohols, and long chain fatty esters were used to support the safety finding for rice bran wax

oxidized as rice bran wax oxidized is a natural substance comprised predominantly of long chain fatty acids, long chain fatty alcohols, and long chain fatty esters. Submitted data consisted of numerous subchronic, chronic, and reproductive/developmental studies on substances including carnauba wax, rice bran wax, a mixture of beeswax long chain alcohols, a mixture of sugar cane wax fatty acids, docosanol, docosanoic acid, and policosanol.

Rice bran wax oxidized was shown to have low acute oral toxicity. There were no acute dermal or inhalation studies submitted; however, dermal and eye irritation studies showed the rice bran wax oxidized was not an irritant. Rice bran wax oxidized was also not considered a skin sensitizer in related studies.

No endpoint of concern was identified for any of the acute, subchronic, chronic, or reproductive/developmental studies conducted at any dose level including the limit dose of 1000 mg/kg/day. There was also no evidence of carcinogenicity in any of the studies including chronic studies and studies on mutagenicity and cytotoxicity. In addition, no neuropathological changes or effects were reported in any of the studies. There is also no indication in the database that rice bran wax oxidized will be immunotoxic.

Furthermore, the potential for absorption of rice bran wax via the gastrointestinal (GI) tract is limited. The long-chain fatty acid esters present in plant-based waxes are generally thought to be poorly absorbed in the GI tract as uptake is thought to decrease as chain length and hydrophobicity increase. Rice bran wax is being used as a surrogate for rice bran wax oxidized based on its similar physical and chemical properties and expected potential for toxicity. Similar to rice bran wax, which is poorly absorbed, it is unlikely that rice bran wax oxidized would be systemically available for GI absorption, as both substances are comprised of very long carbon chain lengths which are not absorbed.

#### *B. Toxicological Points of Departure/Levels of Concern*

Available toxicity studies on rice bran wax oxidized indicate that it has a very low acute, subchronic, and chronic toxicity. No adverse effects were seen in any of the studies presented at the limit dose of 1000 mg/kg/day; therefore, no endpoint of concern has been identified for acute, subchronic, or chronic toxicity.

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to rice bran wax oxidized, EPA considered exposure under the proposed exemption from the requirement of a tolerance and other natural sources of rice bran wax. EPA assessed dietary exposures from rice bran wax oxidized in food as follows:

Dietary exposure to rice bran wax oxidized may occur from eating foods naturally containing rice bran wax (which is metabolized by the body to rice bran wax oxidized) and foods treated with pesticide formulations containing rice bran wax oxidized as an inert ingredient. Because no toxicological endpoint of concern was identified for rice bran wax oxidized, a quantitative dietary exposure assessment for rice bran wax oxidized was not conducted.

2. *Dietary exposure from drinking water.* Although drinking water exposures from use of pesticide formulations containing rice bran wax oxidized on food crops is possible, an endpoint of concern was not identified for the acute or chronic dietary assessment; therefore, a quantitative dietary exposure risk assessment for drinking water was not conducted.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). Rice bran wax oxidized may be used as inert ingredient in pesticide products that are registered for specific uses that may result in indoor or outdoor residential exposures. Since there are no toxicological effects of



concern at the limit dose in available studies, a quantitative assessment of residential (non-occupational) exposures and risks is not necessary.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

Rice bran wax oxidized does not have toxic mode of action and therefore, cumulative risk assessment is not necessary.

#### *D. Safety Factor for Infants and Children*

Section 408(b)(2)(C) requires EPA to retain an additional tenfold margin of safety in the case of threshold effects to ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. As noted in Unit IV.B., there is no indication of threshold effects being caused by rice bran wax oxidized at the limit dose. Therefore, due to the lack of any toxicological endpoints of concern at the limit dose, EPA is conducting a qualitative assessment of rice bran wax oxidized which does not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

#### *E. Aggregate Risks and Determination of Safety*

Taking into consideration all available information on rice bran wax oxidized, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to rice bran wax oxidized under reasonably foreseeable circumstances. Therefore, the establishment of exemptions from the requirement of a tolerance under 40 CFR 180.910, 180.930, and 180.940(a) for residues of waxes and waxy

substances, rice bran, oxidized when used as an inert ingredient in pesticide formulations applied pre- and post-harvest, on animals, and in antimicrobial formulations (food-contact surface sanitizing solutions), is safe under FFDCA section 408.

## **V. Other Considerations**

### *A. Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

### *B. Response to Comments*

One comment was received in response to the Notice of Filing, generally stating that exposure to unnecessary pesticides needs to be decreased. The Agency recognizes that some individuals believe that pesticides should be limited or banned on agricultural crops. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has provided no information that would support a conclusion that these exemptions are not safe.

## **VI. Conclusions**

Therefore, exemptions from the requirement of a tolerance are established under 40 CFR 180.910, 180.930, and 180.940(a) for residues of waxes and waxy substances, rice bran, oxidized (CAS Reg. No. 1883583-80-9) when used as an inert ingredient (flow aid, surface protectant, film-forming agent, carrier, coating agent, or adjuvant) in pesticide formulations

applied to growing crops and raw agricultural commodities after harvest, to animals, and in antimicrobial formulations (food-contact surface sanitizing solutions).

## **VII. Statutory and Executive Order Reviews**

This action establishes an exemption from the requirement of a tolerance under FFDCa section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCa section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power

and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

#### **VIII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 21, 2018.

Donna Davis,  
*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In §180.910, add alphabetically the inert ingredient “Waxes and waxy substances, rice bran, oxidized (CAS Reg. No. 1883583-80-9)” to the table to read as follows:

**§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
* * *	* *	* *
Waxes and waxy substances, rice bran, oxidized (CAS Reg. No. 1883583-80-9)		Flow aid, surface protectant, film-forming agent, carrier, coating agent, or adjuvant
* * *	* *	* *

3. In § 180.930, add alphabetically the inert ingredient “Waxes and waxy substances, rice bran, oxidized (CAS Reg. No. 1883583-80-9)” to the table to read as follows:

**§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
* * *	* *	* *
Waxes and waxy substances, rice bran, oxidized (CAS Reg. No. 1883583-80-9)		Flow aid, surface protectant, film-forming agent, carrier, coating agent, or adjuvant
* * *	* *	* *

4. In § 180.940(a), add alphabetically the inert ingredient “Waxes and waxy substances, rice bran, oxidized” to the table to read as follows:

**§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).**

\* \* \* \* \*

(a) \* \* \*

Pesticide Chemical	CAS Reg. No.	Limits
* * *	* *	* *
Waxes and waxy substances, rice bran, oxidized	1883583-80-9	None
* * *	* *	* *

\* \* \* \* \*

[FR Doc. 2019-03295 Filed: 2/25/2019 8:45 am; Publication Date: 2/26/2019]